



10/544259 PCT  
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Atty. Dkt. No. MARKS0801  
(041376-0801)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Alterschopfer and Watkinson

Title: TRANSDERMAL  
GRANISETRON

Appl. No.: 10/544,259

Filing Date: 08/03/2005

Examiner: Not yet assigned

Art Unit: 1732

Conf. No. 1348

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| <p><b>CERTIFICATE OF MAILING</b></p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.</p> <p><u>Stephen E. Reiter</u><br/>(Printed Name)</p> <p><u>Stephen E. Reiter</u><br/>(Signature)</p> <p><u>4/4/06</u><br/>(Date of Deposit)</p> |
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**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

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P.O. Box 1450  
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Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to

antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

The relevance of the foreign-language documents is described in the present specification. An English translation of the foreign-language documents is not readily available. However, the absence of such translation does not relieve the PTO from its duty to consider the submitted foreign language documents (37 CFR §1.98 and MPEP §609).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 50-0872.

Respectfully submitted,

Date 4/4/06

By Stephen E. Reiter

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Stephen E. Reiter  
Attorney for Applicant  
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|  |   |    |   | Application Number       | 10/544,259              |
|  |   |    |   | Filing Date              | August 3, 2005          |
|  |   |    |   | First Named Inventor     | Peter Altenschopfer     |
|  |   |    |   | Group Art Unit           |                         |
|  |   |    |   | Examiner Name            |                         |
| Sheet  | 1 | of | 2 | Attorney Docket Number   | MARKS0801 (041376-0801) |

**U.S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | U.S. Patent Document |                                   | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines, Where Relevant<br>Passages or Relevant Figures Appear |
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|                    |                       | Number               | Kind Code <sup>2</sup> (if known) |   |   |  |
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**U.S. PATENT APPLICATION DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | U.S. Patent Application Document |                                   | Name of Patentee or Applicant of Cited Document | Filing Date of Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines, Where Relevant<br>Passages or Relevant Figures Appear |
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**FOREIGN PATENT DOCUMENTS**

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|--------------------|-----------------------|-------------------------|---------------------|-----------------------------------|--|---|--|----------------|
|                    |                       | Office <sup>3</sup>     | Number <sup>4</sup> | Kind Code <sup>5</sup> (if known) |  |   |  |                |
| /S.T./             | A1                    | WO                      | 94/07468            |                                   | Cygnus Therapeutic Systems                       | 04-14-1994  |  |                |
| /S.T./             | A2                    | WO                      | 98/53815            |                                   | Minnesota Mining and Manufacturing Company       | 12-03-1998  |  |                |
| /S.T./             | A3                    | WO                      | 00/47208            |                                   | Samyang Corporation                              | 08-17-2000  |  |                |
| /S.T./             | A4                    | WO                      | 01/74338            |                                   | LTS Lohmann Therapie-Systeme AG                  | 10-11-2001  |  |                |
|                    | A5                    | WO                      | 04/069141 A2        |                                   | Strakan Limited                                  | 08-19-2004  |  |                |
|                    | A6                    | EP                      | 1064939 A           |                                   | Novositis Pharma AG                              | 08-26-2000  |  |                |
|                    | A7                    | JP                      | 8-04784             |                                   |  | 02-06-1998  |  |                |

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>6</sup> |
|--------------------|-----------------------|--|----------------|
| /S.T./             | A8                    | Biswas and Rudra, Comparison of granisetron and granisetron plus dexamethasone for the prevention of postoperative nausea and vomiting after laparoscopic cholecystectomy. Acta Anaesthesiol Scand., 47:79-83, 2003.   |                |

|                    |              |                 |            |
|--------------------|--------------|-----------------|------------|
| Examiner Signature | /Susan Tran/ | Date Considered | 02/22/2008 |
|--------------------|--------------|-----------------|------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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STATEMENT BY APPLICANT

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Sheet 2 of 2

## Complete if Known

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| Examiner Name          |                         |
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## NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>6</sup> |
|--------------------|-----------------------|--|----------------|
| /S.T./             | A9                    | Cupissol et al., Evaluation of the bioequivalence of tablet and capsule formulations of granisetron in patients undergoing cytotoxic chemotherapy for a malignant disease. J.Pharm.Sci., 82:1281-1284, 1993.   |                |
|                    | A10                   | Friedman et al., Oral granisetron for the prevention of acute late onset nausea and vomiting in patients treated with moderately emetogenic chemotherapy. Oncologist, 5:136-143, 2000.   |                |
|                    | A11                   | Gralla et al., Recommendations for the use of antiemetics: Evidence based, clinical practice guidelines. Journal of Clinical Oncology, 17:2971-2994, 1999.   |                |
|                    | A12                   | Guillem et al., High efficacy of oral granisetron in the total control of cyclophosphamide-induced prolonged emesis. Proceedings of the American Society of Oncology, 17:46, 1998.   |                |
|                    | A13                   | Kalaycio et al., Continuous-infusion granisetron compared to ondansetron for the prevention of nausea and vomiting after high-dose chemotherapy. J. Cancer Res. Clin. Oncol., 124:265-269, 1998.   |                |
|                    | A14                   | Noble et al., A double-blind, randomized, crossover comparison of granisetron and ondansetron in 5-day fractionated chemotherapy: assessment of efficacy, safety and patient preference. Eur. J. of Cancer, 30: 1083-1088, 1994.                               |                |
|                    | A15                   | Physicians Desk Reference (2001) entry for Kytril®   |                |
| /S.T./             | A16                   | Porzio et al., Pruritus in a patient with advanced cancer successfully treated with continuous infusion of granisetron. Support Care Cancer, January 21, 2004.   |                |

Examiner  
Signature

/Susan Tran/

Date  
Considered

02/22/2008

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